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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,494	10/19/2000	Kristine B. Fuimaono	39716/KMO/W112	6739

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EXAMINER

RODRIGUEZ, CRIS LOIREN

ART UNIT PAPER NUMBER

3763

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/692,494

Applicant(s)

FUIMAONO ET AL.

Examiner

Cris L. Rodriguez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11, 12, 17, 18, 26, 27, 30-34 and 36-73 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12, 26, 27, 43-46, 52-55 and 57-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17, 18, 30-34, 36-42, 47-51, 56, 61-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 17, 18, 30-42, 47-51, 56, and 62-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haissaguerre et al (US 6,068,629) in view of Swanson et al (US 6,428,537).

Haissaguerre discloses electrophysiology catheters and method for atrial fibrillation treatment in the heart. The catheters have a generally rigid probe body (the proximal end portion is stiffer than the distal end portion), a flexible irrigation tube fixedly attached to the distal end of the probe body and having at least irrigation openings (col. 8, lines 20-30, and in col. 9 line 61 - col. 10 line 3 discloses the use of holes), an infusion tube<sup>75</sup>, and an electrode having a metal ribbon around to irrigation tube (fig. 3, 16A-17, and 19A-B). In figure 19A-B, it is set forth that arms 170,172 are allowed to pivot at a central living hinge at their connection 174 with shaft 6 (Col. 13, lines 50-56). The step of opening the heart of the patient is found in col. 2, lines 43-47. In col. 10, lines 31-35 is disclosed other methods of access into the heart. However, Haissaguerre fails to disclose the irrigation tube forming a loop, the length of the probe and the diameter of the loop, the metal ribbon made of nitinol, and a malleable probe tubular body.

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Swanson teaches electrophysiology catheter systems and probes, and methods for treatment of atrial fibrillation in the heart. Swanson made a distinction between catheters and probes, and also set forth that the catheters configuration can be made as probes (see column 24). Swanson teaches several embodiments, but see more specifically to figs. 9, 11, and 23. It is also included a loop-shaped probe (fig 23), and that the probe tubular body can be rigid or malleable. Also, it is inherent that if the probe is going to be rigid and is going to be used for atrial fibrillation in the heart, the heart has to be opened. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Haissaguerre's catheter's configuration with Swanson's loop configuration, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of atrial fibrillation. *In re Dailey and Eilers*, 149 USPQ 47 (1966). Furthermore, it would have been an obvious matter of design choice to make the catheter with the claimed diameters and length, since such modification would have involved a mere change in the size of the catheter and loop. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955). Also, the selection of a nitinol material for the ribbon has been rendered as an obvious design choice, since the selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945).

***Response to Arguments***

3. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

4. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

5. In response to applicant's arguments that Haissaguerre or Swanson fails to disclose the first and second ends of the irrigation tube is fixedly attached to the distal end of the probe body, it seems to the examiner that this element was clear from the references. However, the examiner will explain in more detail.

- Haissaguerre discloses different kinds of electrophysiology catheters for atrial fibrillation, and their method of using. The catheters include a probe 6 that has fixedly connected arms 30 at its distal end including electrodes 38 and holes for fluid delivery. Both ends of the arms are fixedly attached to the distal end of the probe. Figure 4 discloses the arms including an outer sleeve 96 forming an annular fluid passage with the core 94, and electrodes 38 surrounding the outer sleeve 96. Figures 19A and 19B show a modified design of the central hinge assembly disclosed in the previous embodiments in Haissaguerre.

Swanson is being use to teach what is missing from Haissaguerre. Swanson teaches electrophysiology catheter systems and probes for atrial fibrillation and

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its method of using. Swanson further discloses different shapes such as in figs. 9-11 having several arms with electrodes, and a looped configuration in figures 23 and 27. It is old and well known by Swanson the loop configuration to treat the heart's atrial fibrillation. Therefore, given the teachings, it would have been obvious to one having ordinary skill to modify Haissaguerre's probe with Swanson's loop configuration, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious to treat atrial fibrillation.

6. In response to applicant's argument that Haissaguerre does not teach or suggest connecting the second (distal) ends of the arms to the catheter body, but instead the arms have a free end, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Swanson teaches different shapes of catheter/probes including one with arms and another with a loop configuration. The combination of references would have been obvious.

7. In response to applicant's arguments with respect to claim 64, Figure 19A-B show that arms 170,172 are biased away from each other and that catheter may further include a sleeve to urge the arms 170,172 into parallel configuration (col. 13 lines 40-

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60). This implicit language set forth that the arms does not have any internal support or wire to keep them straight; that's why a sleeve is needed. Therefore, this figure meets the language of claim 64.

**Conclusion**

**8. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

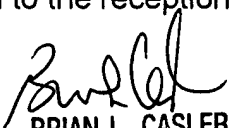
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

November 5, 2003

  
BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700

  
Cris L. Rodriguez  
Examiner  
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